AUG 2 9 2001

510(k) Summary

K012728

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 577-9070

Contact Person: Colleen Hittle

Date: August 6, 2001

807.92(a)(2)

Trade Name: E-Scan

Common Name: Magnetic resonance diagnostic device

Classification Name(s): System, Nuclear Magnetic Resonance Imaging

Classification Number: ~~90LNH~~ 90 MOS

807.92(a)(3)

Predicate Device(s)

Esaote	E-Scan	K001894

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

807.92(a)(5)

Intended Use(s)

The E-scan is intended for diagnostic nuclear magnetic resonance imaging of the hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm and forearm. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

807.92(a)(6)

Technological Characteristics

The Multipurpose Flexible Receiving Coil improves the system performance and does not alter the fundamental scientific technology of the cleared device.

Substantial Equivalence Comparison Table

E-scan With Multipurpose Flexible Receiving Coil	Comments
Shoulder coil No.1: 17.5 x 12.6 x 14.5 cm (w x d x h) Shoulder coil No. 5: 16.8 x 7.9 x 15.5 cm (w x d x h) Multipurpose flexible coil: 22 x 32.5 x 32.5 (short axis x long axis)	The Multipurpose flexible coil substitutes completely the Hip Coil. For its characteristics the flex coil can be used to exam the shoulder and the knee too, especially for patient with painful or in plaster limb. See example for the Flexible body Coil (hip and other regions) – 20x150 cm (wxd) – of the AIRIS HITACHI (K945155)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2001

BioSound Esaote, Inc.
% Ms. Colleen J. Hittle
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K012728
E-Scan MRI System (Receiving Coil)
Dated: August 6, 2001
Received: August 15, 2001
Regulatory Class: II
21 CFR 892.1000/Procode: 90 MOS

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4,xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K012728

Device Name: E-Scan

Indications for Use:

The E-scan is intended for diagnostic nuclear magnetic resonance imaging of the hip, knee, ankle, foot, shoulder, elbow, wrist, hand, calf, thigh, arm and forearm. The device produces transverse, sagittal, coronal and oblique cross-sectional images, displaying the internal structure of the limbs and joints being imaged. The images that are produced correspond to the spatial distribution of protons (hydrogen nuclei) that check the magnetic resonance properties and depend upon the MR parameters (spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and chemical shift). If interpreted by a medical expert, these images can provide diagnostically useful information.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012728